

REMARKS/ARGUMENTS

I. Amendments to the Claims

New claims 14-17 have been added.

Support for dividing dosages and administration prior to meals is found in paragraph 17 of the specification as filed.

No new matter is added by the new claims.

II. Krieder Does Not Anticipate Claims 8-11 and 13 Under 35 U.S.C. §102

Claims 8-13 stand rejected as anticipated by Krieder. Anticipation requires that each and every element of a claim appear in the prior art. Applicant asserts that Krieder fails to teach any of the elements of the present claims.

First, Krieder fails to teach anything with respect to reducing appetite or food intake as required by claims 8-13. In fact Krieder clearly provides "Results revealed no significant differences in caloric intake or macronutrient intake between groups." Page 261. Therefore, Krieder in fact teaches away from the present invention which is for a method of "reducing food intake and appetite for food"

In view of the failure to teach reduction of appetite or food intake, Krieder cannot teach an effective amount of forskolin to achieve these effects. The inventors have taught that the effects of reduction of appetite or food intake only occur at higher levels of forskolin administration. The highest dosage administered in any study reported in Krieder was 50 mg per day as either a 250mg of a 10% forskolin extract (page 260) or two capsules standardized for 25 mg of forskolin (page 261). Applicant has shown that the effective dose for most patients is 75mg per day even though some may see benefit at 30 mg per day and in fact provides working examples at 80mg and 120 mg of forskolin per day.

III. Krieder Does Not Render Claim 12 Obvious Under 35 U.S.C. §103

Claim 12 stands rejected as being obvious in view of Krieder.

Establishment of a *prima facie* case of obviousness requires that the Examiner satisfy three criteria. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combine references. See *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1958 (Fed. Cir. 1988); *In re Skinner*, 2U.S.P.Q.2d 1788, 1790 (Bd. Pat. App. & Int. 1986). Second, the proposed modification of the prior art must have a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991); *In re Erlich*, 3 U.S.P.Q.2d 1011, 1016 (Bd. Pat. App. & Int. 1986). Lastly, the prior art reference or combination of references must teach or suggest all the limitations of the claims. See *In re Zurko*, 111 F.3d 887, 888-89, 42 U.S.P.Q.2d 1476, 1478 (Fed. Cir. 1997). The teachings or suggestions, as well as the expectations of success, must come from the prior art, not applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991).

Further, under Section 103, the art must be taken as a whole. *In re Wesslau*, 147 USPQ 391,393 (CCPA 1965) ("it is impermissible ...to pick and choose from anyone reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."). See also, *Smithkline Diagnostics, Inc. v. Helena Laboratories, Corp.*, 8 USPQ2d 1468, 1475 (Fed. Cir. 1988) ("claims, entire prior art, and prior art patents must be read 'as a whole'"). Also, if the art "teaches away" from a claimed invention, such a teaching supports the nonobviousness of the invention. *US. v. Adams*, 148 USPQ 479 (1966); *Gillette Co. v. S.c. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990).

Krieder fails to teach all of the elements of the present claims. First, Examiner has acknowledged that "Krieger does not teach administration of forskolin at a dose of 75-150mg." Office Action, page 3. Second, no one reading Krieder would understand that the administration of forskolin at any dosage could reduce appetite or reduce food intake because in fact, Krieder unambiguously teaches that there was no reduction in food intake based on forskolin administration: "Results revealed no significant differences in caloric intake or macronutrient intake between groups." Page 261. Applicant's claims are for method of reducing food intake and appetite for food. Therefore, Krieder which does not suggest or teach reduction of food intake and in fact which shows no difference in food intake, necessarily teaches away from the present invention.

CONCLUSION

Applicant submits that these amendments and remarks, when entered, place claims 8-21 in condition for allowance and respectfully request that such action be taken by the Examiner at this time. Applicant requests that Examiner contact Applicant's attorney to discuss this matter if the claims are not deemed allowable.

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